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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/809,483	03/15/2001	Kurt R. Linberg	P-8945	5644

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EXAMINER	
NAJARIAN, LENA	
ART UNIT	**PAPER NUMBER**
3626	

DATE MAILED: 05/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/809,483	LINBERG ET AL.	
	Examiner	Art Unit	
	Lena Najarian	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 March 2001*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 2 and 12-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claims 2 and 12-13 recite the limitations for which there is no antecedent basis in the claims. In particular, the following passages lack or have vague antecedent basis:

(i) "the patient data": claim 2, line 2

(ii) "the security protocol": claim 12, line 1

claim 13, line 1.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-9, 16, 19, and 21 are rejected under 35 U.S.C. 102(e) as being anticipated by Snell (US 6,249,705 B1).

(A) Referring to claim 1, Snell discloses a data communications server system, comprising (col. 6, lines 50-65 of Snell):

a computerized network of patient nodes and clinician nodes (col. 5, lines 7-17, col. 11, lines 49-59, and Fig. 3 of Snell; the Examiner interprets "physician" to be a form of "clinician"); and

means for the consolidation and distribution of individual or aggregate patient scheduling, treatment regimens, and outcome data (col. 11, lines 4-7 and col. 1, lines 34-49 & 45-58 of Snell; the Examiner interprets "appropriate therapy" to be a form of "treatment regimens" and "historical data" to be a form of "outcome data").

(B) Referring to claim 2, Snell discloses wherein at least a portion of the patient data is collected by implanted medical devices (col. 1, lines 30-34 of Snell; the Examiner interprets "pacemaker" to be a form of "implanted medical device").

(C) Referring to claim 3, Snell discloses wherein the treatment regimens distributed comprise instructions to implanted medical devices (col. 1, lines 34-39 of Snell; the Examiner interprets "programming" to be a form of "comprise instructions").

(D) Referring to claim 4, Snell discloses a computerized method of collecting and utilizing distributed patient and clinician data, comprising the steps of:

a. providing a data communications network having a plurality of nodes from which each node may access, directly or indirectly, a central server system (Fig. 3 and col. 4, lines 32-34 of Snell);

b. providing to the network plurality of nodes a computerized interface to resources of the server (Fig. 2, item 130 of Snell);

c. gathering via at least one of said plurality of nodes of the network node computerized interfaces individual patient information (col. 1, lines 29-34 of Snell; the Examiner interprets "electrical heart signals" to be a form of "patient information");

d. aggregating the patient information (col. 2, lines 52-54 of Snell); and

e. distributing the patient information to network nodes administered by clinicians (col. 4, lines 11-14 of Snell; the Examiner interprets "physician" to be a form of "clinician").

(E) Referring to claim 5, Snell discloses wherein the central server system comprises a network of servers (col. 6, lines 5-13 of Snell).

(F) Referring to claim 6, Snell discloses wherein the computerized interface to the central server system is implemented as a html browser utility (col. 2, lines 52-57 of Snell; the Examiner interprets "browser over the Internet" to be a form of "html browser utility").

(G) Referring to claim 7, Snell discloses wherein the resources of the central server system comprise a body of empirical data regarding implantable medical devices (col. 1, lines 30-34 and col. 5, lines 38-41 of Snell).

(H) Referring to claim 8, Snell discloses wherein the resources of the central server system further comprise a system of comparing and analyzing the body of empirical data (col. 4, lines 55-61 of Snell).

(I) Referring to claim 9, Snell discloses wherein the empirical data regarding implanted medical devices comprises data identifiable to individual patients (col. 2, lines 48-54 of

Snell; the Examiner interprets "generate reports on one patient or a group of patients" to be a form of "data identifiable to individual patients").

(J) Referring to claim 16, Snell discloses wherein the step of aggregating the patient information further comprises the step of removing patient data that may provide individual identification of a patient (col. 7, lines 63-65 of Snell; the Examiner interprets "anonymous" to be a form of "removing patient data that may provide individual identification of a patient").

(K) Referring to claim 19, Snell discloses a computerized method of communicating in real time between patients, clinicians, and implanted medical devices comprising the steps of (see abstract of Snell):

a. capturing patient implanted device data;

b. storing the implanted device data on a central server system;

c. analyzing and distributing aggregate patient implanted device information (col. 2, lines 48-61 of Snell);

d. displaying patient-specific data in real time over a public network (col. 2, lines 52-54 of Snell; the Examiner interprets "Internet" to be a form of "public network"); and

e. dispensing therapeutic and clinical care based upon the implanted medical device information (col. 1, lines 30-39 of Snell).

(L) Referring to claim 21, Snell discloses wherein the displaying of patient specific data over a public network is done using a secure protocol with an authenticated client (col. 7, lines 41-54 of Snell).

6. Claim 17 is rejected under 35 U.S.C. 102(e) as being anticipated by Bardy (US 6,331,160 B1).

(A) Referring to claim 17, Bardy discloses a real-time information management system for implantable medical devices (IMDs), comprising (see abstract of Bardy & col. 8, lines 5-18 of Bardy):

a computerized data communication server network that allows patients to view, analyze and display data stored on their IMDs (col. 3, lines 44-50 and Fig. 1 of Bardy);

a server-based interface to disseminate to patients information about their IMDs (col. 6, lines 6-10 and col. 7, lines 26-34 & 63-65 of Bardy);

means for chronic heart rhythm monitoring (col. 1, lines 30-37 of Bardy); and

means for provision of consultation for therapy and clinical care in real-time (col. 2, lines 10-17 and col. 1, lines 33-37 of Bardy).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 10-11 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Snell (US 6,249,705 B1) as applied to claims 4, 7, 9, and 19 above, in view of Bardy (US 6,331,160 B1).

(A) Referring to claim 10, Snell does not disclose wherein the data identifiable to individual patients may be accessed by the individual patients to which this data pertains.

Bardy discloses wherein the data identifiable to individual patients may be accessed by the individual patients to which this data pertains (col. 7, lines 26-34 of Bardy).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the feature of Bardy within Snell. The motivation for doing so would have been to provide feedback to the patients (col. 7, lines 27-28 of Bardy).

(B) Referring to claim 11, Snell discloses wherein the data identifiable to individual patients is protected by a encryption protocol when accessed (col. 7, lines 41-54 of Snell).

(C) Referring to claim 20, Snell does not disclose wherein the patient is able to monitor clinical care and therapy.

Bardy discloses wherein the patient is able to monitor clinical care and therapy (col. 3, lines 45-50 and col. 4, lines 62-65 of Bardy).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the features of Bardy within Snell. The motivation for doing so would have been to facilitate holistic, remote, automated patient care (col. 4, lines 62-65 of Bardy).

9. Claims 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Snell (US 6,249,705 B1) in view of Bardy (US 6,331,160 B1) as applied to claims 10-11 above, and further in view of Tan et al. (US 2001/0045451 A1).

(A) Referring to claims 12 and 13, Snell and Bardy do not disclose wherein the security protocol protecting the data identifiable to individual patients is a secure socket layer and wherein the security protocol protecting the data identifiable to individual patients is the https protocol.

Tan discloses wherein the security protocol protecting the data identifiable to individual patients is a secure socket layer and wherein the security protocol protecting the data identifiable to individual patients is the https protocol (para. 28, line 22, para. 8, lines 10-14 and para. 32, lines 15-16 of Tan).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the features of Tan within Snell and Bardy. The motivation for doing so would have been to provide secure user access (para. 6 of Tan) and a secure web site (para. 32, lines 15-16 of Tan).

(B) Referring to claim 14, Snell and Bardy do not disclose wherein a user attempting to access data identifiable to an individual patient must authenticate themselves prior to receiving the data.

Tan discloses wherein a user attempting to access data identifiable to an individual patient must authenticate themselves prior to receiving the data (see abstract of Tan).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the feature of Tan within Snell and Bardy. The motivation for doing so would have been to verify the identity of the user (abstract of Tan).

(C) Referring to claim 15, Snell and Bardy do not disclose wherein the authentication to which a user is subject comprises strong authentication.

Tan discloses wherein the authentication to which a user is subject comprises strong authentication (para. 6 of Tan; the Examiner interprets "token based user access authentication" to be a form of "strong authentication").

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the feature of Tan within Snell and Bardy. The motivation for doing so would have been to enable secure user access to a web server (para. 6 of Tan).

10. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bardy (US 6,331,160 B1) as applied to claim 17, in view of Snell (US 6,249,705 B1).

(A) Referring to claim 18, Bardy does not disclose wherein the information about patient IMDs comprises technology developments, clinical trials, and support-group information.

Snell discloses wherein the information about patient IMDs comprises technology developments, clinical trials, and support-group information (col. 1, lines 59-63, col. 5, lines 45-53, and col. 8, lines 41-47 of Snell; the Examiner interprets "upgrade the programmer" to be a form of "technology developments," "clinical studies" to be a form of "clinical trials," and "presses HELP" to be a form of "support-group information").

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the features of Snell within Bardy. The motivation for doing so would have been to provide information on enhanced features (col. 1, lines 59-61 of Snell), to gain FDA approval for implantable medical devices (col. 5, lines 45-49 of Snell), and to provide an on-line manual (col. 8, lines 44-47 of Snell).

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The cited but not applied prior art teaches an enhanced medical treatment system (US 2003/0055679 A1).

Also included is provisional application 60/185,579, which is a priority document to applied reference, US 2001/0045451 A1 (Tan et al.).

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lena Najarian whose telephone number is (571) 272-7072. The examiner can normally be reached on Monday - Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on (571) 272-6776. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

LN
In
4-28-05

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